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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,783	02/28/2005	Richard Keith	100822-1P US	8524

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,783	KEITH, RICHARD	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted October 18, 2006 wherein claims 1-14 and 16-23 are cancelled, claim 15 is amended, and new claims 24-28 are introduced. This application is a national stage entry of PCT/SE03/01352, filed September 1, 2003, which claims benefit of foreign application SE020259809, filed September 2, 2002.

Claims 15 and 24-28 are pending in this application.

Claims 15 and 24-28 are examined on the merits herein.

Applicant's amendment submitted October 18, 2006 with respect to the rejections of instant claims 17-22 under 35 USC 112, first paragraph for lacking enablement, has been fully considered and found to be persuasive to remove the rejections as the rejected claims are no longer pending.

Applicant's amendment submitted October 18, 2006 with respect to the rejections of instant claims 13, 14, 16, 20, and 22 under 35 USC 103 being obvious over Phillips in view of Jick, has been fully considered and found to be persuasive to remove the rejections as the rejected claims are no longer pending.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US patent 5902814, cited in PTO-892) in view of Jick et al. (Included with PTO-1449) further in view of Stalker et al. (Reference included with PTO-892) Gordon et al. discloses a number of spiro-azabicyclo[2.2.2]octane compounds, including spiro[1-azabicyclo[2.2.2]octane-3,5'-oxazolidine]-2'-one hydrochloride. (column 1, lines 30-49, column 6, line 33 – column 7, line 33) These compounds are useful in the manufacture of a medicament for the treatment of a number of conditions including Alzheimer's disease. (column 4, lines 27-41, column 5, lines 10-16) Gordon et al. does not disclose a combination of this compound with rosuvastatin, a pharmaceutical composition comprising such a combination, or a method of treating Alzheimer's disease using such a composition.

Jick et al. discloses that subjects who were taking statins (HMG-CoA reductase inhibitors) in order to reduce cholesterol experienced a statistically significant reduction in their incidence of dementia such as Alzheimer's disease. (p. 1629, right column) This effect was determined to be independent of external factors such as the patients' lipid levels.

Stalker et al. discloses that Rosuvastatin, like simvastatin, lovastatin, and fluvastatin, is an HNG-CoA reductase inhibitor.

It would have been obvious to one of ordinary skill in the art to modify the invention of Gordon et al. by combining spiro[1-azabicyclo[2.2.2]octane-3,5'-oxazolidine]-2'-one hydrochloride with rosuvastatin to produce the combinations described by instant claims 15 and 24, and the pharmaceutical composition of claim 26, and by administering the composition to a patient suffering from Alzheimer's disease as described by instant claims 27 and 28. One of ordinary skill in the art would have been motivated to produce this combination because spiro[1-azabicyclo[2.2.2]octane-3,5'-oxazolidine]-2'-one hydrochloride and statins were known to be useful for the treatment of Alzheimer's disease and because Stalker et al. discloses that rosuvastatin functions by the same mechanism as other statins mentioned by Jick et al. as being useful for treating Alzheimer's disease. One of ordinary skill in the art would reasonably have expected success because combining known therapeutic compounds, adding a pharmaceutically acceptable carrier, and administering the composition to a patient is well within the ordinary and routine level of skill in the art.

It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 15, 25, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (PCT international publication WO9854189, included with PTO-892) in view of Jick et al. (Included with PTO-1449) further in view of Stalker et al. (Reference included with PTO-892)

Peters et al. discloses a range of nicotininc receptor agonists useful for treating a number of diseases including Alzheimer's disease and Parkinson's disease. (p. 4, lines 25-36) The compounds have a general formula which includes (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] within its general teaching. (p. 5, line 24 – p. 6, line 15, p. 9, lines 14-21) Peters et al. does not teach a composition of (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] and rosuvastatin or a method of treating Alzheimer's or Parkinson's disease by administering such a composition.

Jick et al. discloses that subjects who were taking statins (HMG-CoA reductase inhibitors) in order to reduce cholesterol experienced a statistically significant reduction in their incidence of dementia such as Alzheimer's disease. (p. 1629, right column) This effect was determined to be independent of external factors such as the patients' lipid levels.

Stalker et al. discloses that Rosuvastatin, like simvastatin, lovastatin, and fluvastatin, is an HNG-CoA reductase inhibitor.

It would have been obvious to one of ordinary skill in the art to modify the invention of Peters et al. by combining (2'R)-5'-(3-furanyl)spiro[1-

azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] with rosuvastatin to produce the combinations described by instant claims 15 and 25, and the pharmaceutical composition of claim 26, and by administering the composition to a patient suffering from Alzheimer's disease as described by instant claims 27 and 28. One of ordinary skill in the art would have been motivated to produce this combination because (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] and statins were known to be useful for the treatment of Alzheimer's disease in the prior art and because Stalker et al. discloses that rosuvastatin functions by the same mechanism as other statins mentioned by Jick et al. as being useful for treating Alzheimer's disease. One of ordinary skill in the art would have been motivated to specifically use (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] in the composition because this compound is within the general range of compounds disclosed by Peters et al. to be useful for treating Alzheimer's disease. One of ordinary skill in the art would reasonably have expected success because combining known therapeutic compounds, adding a pharmaceutically acceptable carrier, and administering the composition to a patient is well within the ordinary and routine level of skill in the art.

It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Claims 15, 25, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eifion et al. (US patent application publication US2003/0018042 A1, cited in PTO-892) in view of Jick et al. (Included with PTO-1449) further in view of Stalker et al. (Reference included with PTO-892)

Peters et al. discloses the compound (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine]. (p. 1, paragraphs 0007-0009) This compound is useful for the treatment of Alzheimer's disease (paragraphs 0017 and 0023) and may be prepared as a pharmaceutical composition along with a pharmaceutically acceptable carrier. (paragraphs 0028-0035) Peters et al. does not teach a composition of (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] and rosuvastatin or a method of treating Alzheimer's or Parkinson's disease by administering such a composition.

Jick et al. discloses that subjects who were taking statins (HMG-CoA reductase inhibitors) in order to reduce cholesterol experienced a statistically significant reduction in their incidence of dementia such as Alzheimer's disease. (p. 1629, right column) This effect was determined to be independent of external factors such as the patients' lipid levels.

Stalker et al. discloses that Rosuvastatin, like simvastatin, lovastatin, and fluvastatin, is an HNG-CoA reductase inhibitor.

It would have been obvious to one of ordinary skill in the art to modify the invention of Peters et al. by combining (2'R)-5'-(3-furanyl)spiro[1-

azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] with rosuvastatin to produce the combinations described by instant claims 15 and 25, and the pharmaceutical composition of claim 26, and by administering the composition to a patient suffering from Alzheimer's disease as described by instant claims 27 and 28. One of ordinary skill in the art would have been motivated to produce this combination because (2'R)-5'-(3-furanyl)spiro[1-azabicyclo[2.2.2]octane-3,2'-(3'H)-furo[2,3-b]pyridine] and statins were known to be useful for the treatment of Alzheimer's disease in the prior art and because Stalker et al. discloses that rosuvastatin functions by the same mechanism as other statins mentioned by Jick et al. as being useful for treating Alzheimer's disease. One of ordinary skill in the art would reasonably have expected success because combining known therapeutic compounds, adding a pharmaceutically acceptable carrier, and administering the composition to a patient is well within the ordinary and routine level of skill in the art.

It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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